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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,054		Peter Joseph Cassidy	080056-00020	3789

7590 04/05/2006

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EXAMINER

GROSS, CHRISTOPHER M

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/647,054		CASSIDY ET AL.	
	Examiner		Art Unit	
	Christopher M. Gross		1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-144 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 113, 119-127 and 134-144 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 108, 113, 119-127 and 134-144 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/25/2000</u> . | 6) <input type="checkbox"/> Other: _____ |

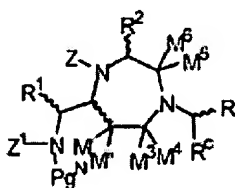
Continuation of Disposition of Claims: Claims withdrawn from consideration are 34-112, 114-118, 122, 123, 125, 127-133, 136, 139 and 141-144.

DETAILED ACTION

Responsive to communication entered 12/22/2005. Claims 109-112 are hereby entered. Claims 34-144 are pending. Claims 34-112, 114-118, 122-123, 125, 127-133, 136, 139, 141-144 are withdrawn. Claims 113, 119, 120, 121, 124, 126, 134, 135, 137, 138 and 140 are examined herein.

Election/Restrictions

Applicant's election with traverse of the invention consisting of claims 113, 119-127 and 134-144 and the species:



wherein R = CH₂CH(CH₃)₂, R₁ is H, R₂ is benzyl, Z and Z' are H, M', M'', M₃, M₄ are H, M₅ and M₆ are taken together with the carbon atom to which they are attached to form a carbonyl group, R_C is COOMe, PgN is Boc, therein reading on claims 113, 119, 120, 121, 124, 126, 134, 135, 137, 138 and 140, in the reply filed on 12/22/2005 is acknowledged.

The restriction traversal concerning the addition of claim 108 is on the ground(s) that the monocyclic core, shown above, structure comprising claim 113, and a library thereof should be examined together.

This is not found persuasive because the invention consisting of claim 108 is distinct from the invention consisting of claims 113, 119-127 and 134-144. The library of claim 108 is best suited toward determining structure activity relationships. Whereas the

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defined structure(s) found in claims 113, 119-127 and 134-144, provide individually unique properties, such as dissociation constants, pharmacological half life, etc. which is not possible to determine with the library consisting of claim 108. In addition to the divergent subject areas, prior art searches of the two inventions are not coextensive: the structure search for the invention consisting of claims 113, 119-127 and 134-144 would not cover the entirety of the library consisting of claim 108.

Claims 34-112, 114-118, 122-123, 125, 127-133, 136, 139, 141-144 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim.

Priority

This is a 35 USC 371 application which claims priority to Australian patent PP2548 (filed 03/24/1998). Whereas the priority papers have been received, the acceptance notice from DO/EO is missing from the file. It is noted that the Acceptance Notice entered 2/21/2001 was rescinded on 8/16/2002.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

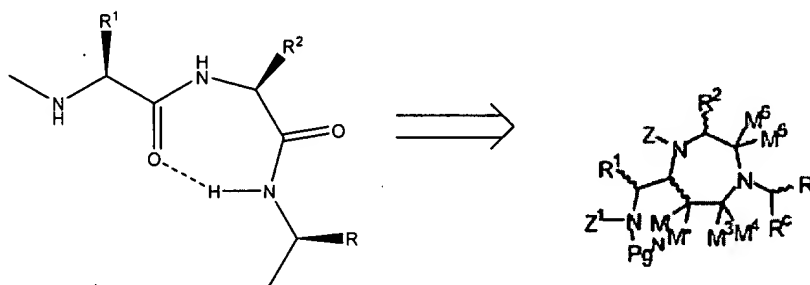
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 113, 119, 120, 121, 124, 126, 134, 135, 137, 138 and 140 are rejected under 35 U.S.C. 102(b) as being anticipated by Ma et al (1995 Protein Peptide Letters 2:347-350).

The claimed invention is drawn to a protein gamma turn mimetic, in which the hydrogen bond, shown on the left, is replaced by two methylene groups, so as to form the 1,4 diazacycloheptane derivative, shown on the right:



Claims 119, 120, 121, 124, 126, 134, 135, 137, 138 and 140 represent variations thereof.

Ma et al, throughout the publication and especially the target molecule and scheme 2, teach the same 1,4 diazacycloheptane mimetic bearing the tripeptide sequence Boc-Ile-Ala/Asp-Gly-OH; therein comprising R groups being amino acid side chains, Z and Z' being H, M', M'', M3, M4 being H, M5 and M6 are taken together with the carbon atom to which they are attached to from a carbonyl group, RC is the carboxy terminus of the mimetic, PgN is the Boc N terminal protecting group. Therefore the structure disclosed by Ma et al reads on claims 113, 121, 134, 135, 137 and 138.

Ma et al teach C-terminal protection as an ethyl ester, reading on the protecting group of claim 119 and alkoxy group of claim 120, as well as the protecting group of claim 124, 126 and 140.

Claim Rejections - 35 USC § 103

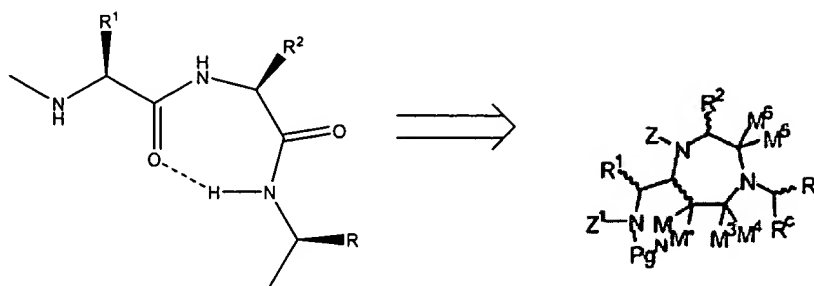
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

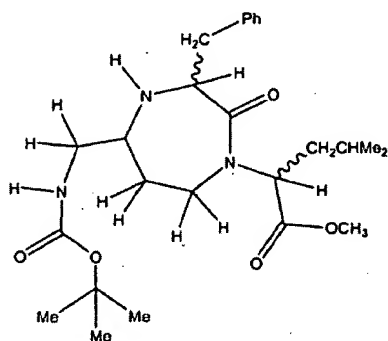
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 113, 119, 120, 121, 124, 126, 134, 135, 137, 138 and 140 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gardner et al (1993 Tetrahedron 49:3433-3448 – IDS entry 9/25/2000) in view of Alkorta et al (1996 J. Molecular Modeling 2:16-25).

The claimed invention is drawn to a protein gamma turn mimetic, in which the hydrogen bond, shown on the left, is replaced by two methylene groups, so as to form the 1,4 diazacycloheptane derivative, shown on the right:



Claims 119, 120, 121, 124, 126, 134, 135, 137, 138 and 140 represent variations thereof. The elected species of the instant invention, shown below:



comprises the tripeptide sequence Gly-Phe-Leu.

Gardner et al, throughout the publication and especially scheme 2, teach Gly-Phe-Leu and prepare a turn mimetic.

Garndner et al do not teach the 1,4 diazacycloheptane gamma turn mimetic, shown above, however.

Alkorta et al., throughout the document and especially figure 2, compound 6 teach a molecular dynamics simulation using a variety of gamma turn mimetics, including 1,4 diazacycloheptane.

It would have been *prima facie* obvious for one of ordinary skill in the art, at the time the claimed invention was made to incorporate the Gly-Phe-Leu sequence of

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Gardner et al. into the simulation comprising the 1,4 diazacycloheptane turn mimetic of Alkorta et al.

One of ordinary skill in the art would have been motivated to use the Gly-Phe-Leu sequence of Gardner et al in the simulation comprising the 1,4 diazacycloheptane turn mimetic of Alkorta et al because Gly-Phe-Leu represents a sequence from leu-enkephalin (the endogenous ligand for the opioid receptor binding Morphine) and conformationally restricted enkephalin analogs better represent the bioactive conformation, as noted by Gardner et al on page 3438.

One of ordinary skill in the art could incorporate the Gly-Phe-Leu sequence of Gardner et al. into the simulation comprising the 1,4 diazacycloheptane turn mimetic of Alkorta et al. with a reasonable expectation of success since the tripeptide analog is not significantly larger, thus computation time would remain tractable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Gross whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher M Gross
Examiner
Art Unit 1639

cg



MARK SHIBUYA, PH.D.
PATENT EXAMINER